



Docket No. 49498-C (72015)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Elliot Danforth Jr. and Albert Burger

Serial No.: 10/715,586

Group No.: Not Yet Assigned

Filed: November 17, 2003

Examiner: Not Yet Assigned

For: PHARMACEUTICAL COMPOSITIONS OF TETRAC AND METHODS
OF USE THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date 2/23/04

By: Lee Dunkle
Lee Dunkle

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- X (1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or
- (2) within three months of the mailing date of the Written Opposition issued by the: _____ Patent Office (dated _____); or

- (3) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application. Copies of these documents (CHECK ONE):

- are enclosed herewith; or
- X have been cited in the parent application, and are thus not being resubmitted herein.

Early examination and allowance of the present application are respectfully solicited.

FEE AUTHORIZATION

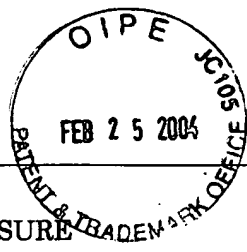
Should any fees associated with the submission be required, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 04-1105. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,



Christine C. O'Day (Reg. 38,256)
EDWARDS & ANGELL, LLP
P.O. Box 55874
Boston, MA 02205
(617) 439-4444

Date: 2-23-04



FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	DOCKET NO: 49498-C (72015)	SERIAL NO.: 10/715,586
	APPLICANT(S): DANFORTH et al.	
	FILING DATE: November 17, 2003	GROUP NO. Unassigned

UNITED STATES PATENT DOCUMENTS

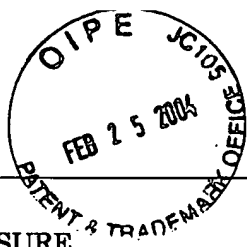
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,426,453	01.17.1984	Cree et al	436/500	436/542	08.27.1981
	AB	4,490,221	12.25.1984	Collange et al	204/72,59R	73 R	04.28.1983
	AC	4,666,702	05.19.1987	Junginger	424/497	424/473	04.11.1985
	AD	4,741,897	05.03.1988	Andrews et al	424/1.1	435/7	07.08.1986
	AE	5,200,428	04.06.1993	Horst	A61K	031/195	08.23.1991
	AF	5,324,522	06.28.1994	Krenning et al	424/456	424/426	12.28.1992
	AG	5,371,102	12.06.1994	Doerge	514/387	514/274	08.06.1993
	AH	5,714,142	02.03.1998	Blaney et al	424/85.2	424/85.4	06.13.1996
	AI	5,736,576	04.07.1998	Kun et al	514/570	514/568	06.04.1996
	AJ	5,910,569	06.08.1999	Latham et al	530/324	530/326	08.25.1997
	AK	6,017,958	01.25.2000	Kun et al	514/532	514/535	04.03.1997

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO
	BA	WO 96/40,048	12.19.1996	PCT	A61K	7/48	
	BB	WO 99/43,307	09.02.1999	PCT	A61K	9/64	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PP., ETC.)

	CA	Takeda et al; Department of Medicine, University of Chicago, Illinois 60637 USA " <u>Triiodothyroacetic Acid Has Unique Potential For Therapy Of Resistance To Thyroid Hormone.</u> " J Clin Endocrinol Metab. 1995 Jul;80(7):pp. 2033-40.
	CB	Ueda et al; First Department of Internal Medicine, Osaka Medical College, Takatsuki, Japan, " <u>Differences in Response of Thyrotropin to 3,5,3'-Triiodothyronine and 3,5,3'Triiodothyroacetic Acid in Patients with Resistance to Thyroid Hormone</u> " Thyroid 1996 Dec;6(6):pp. 563-70.
	CC	Darendeliler et al, Istanbul Faculty of Medicine, Department of Pediatrics, Turkey, " <u>Successful Therapy with 3,5,3'-Triiodothyroacetic Acid (TRIAc) in Pituitary Resistance to Thyroid Hormone</u> ". J Pediatr Endocrinol Metab 1997 Sep-Oct;10(5):pp. 535-8.
	CD	Pujol et al " <u>Prevention of Thyroid Neoplasm Recurrence with Triac and Levothyroxine [letter].</u> " Clin Endocrinol (Oxf) 1997 Jan;46(1): pp.121-2.
	CE	Crossley et al;" <u>Serum Tetraiodothyroacetate (T4A) Levels in Normal Healthy Euthyroid Individuals Determined by Gas Chromatography-Mass Fragmentography (GC- MF).</u> " Clin Chim Acta 1979 Jun 15;94(3):pp. 267-72.
	CF	Juge-Aubry et al; Department of Medicine, Hopital Cantonal Universitaire, Geneva, Switzerland, Eur J." <u>Long-Lasting Effects of Triac and Thyroxine on the Control of Thyrotropin and Hepatic Deiodinase Type I.</u> " Endocrinol 1995 Jun;132(6):pp.751-8
		EXAMINER: DATE:



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INFORMATION DISCLOSURE		APPLICANT(S): DANFORTH et al.	
STATEMENT		FILING DATE: November 17, 2003	GROUP NO. Unassigned
CG	Everts et al; Department of Internal Medicine, Erasmus University Medical School, Rotterdam, The Netherlands, <u>Uptake of Triiodothyroacetic Acid And Its Effect On Thyrotropin Secretion In Cultured Anterior Pituitary Cells</u> . Endocrinology 1994 Dec;135(6): pp. 2700-7.		
CH	Mechelany et al; Institute Gustave-Roussy, Villejuif, France. <u>"Triac (3,5,3'-Triiodothyroacetic acid) has Parallel Effects at the Pituitary and Peripheral Tissue Levels in Thyroid Cancer Patients Treated with L-Thyroxine."</u> Clin Endocrinol (Oxf) 1991 Aug;35(2): pp. 123-8		
CI	Menegay et al; <u>"Pharmacokinetics of 3,5,3'-Triiodothyroacetic Acid and its Effects on Serum TSH Levels"</u> Thyroid Research Unit, Division of Endocrinology, Department of Medicine, University of Geneva, Switzerland. Acta Endocrinologica (Copenh) 1989, 121:pp. 651-658.		
CJ	Ramsden et al; <u>"Serum Concentration of 3,5,3',5'-Tetraiodothyroacetate (T⁴A) in Subjects with Hypo-, Hyper- and Euthyroidism"</u> Department of Medicine, University of Birmingham, Queen Elizabeth Hospital, Birmingham B15 2TH, UK, Acta Endocrinologica 1986, 112: pp. 192-196.		
CK	Gharib et al; <u>"Thyroxine Suppressive Therapy in Patients with Nodular Thyroid Disease: Ann Intern Med.</u> 1998;128:pp. 386-394.		
CL	Pittman et al; <u>"The Nondeiodinative Pathways of Thyroxine Metabolism 3,5,3',5'-Tetraiodothyroacetic Acid Turnover in Normal and Fasting Human Subjects"</u> Journal of Clinical Endocrinology and Metabolism, Copyright 1980 by the Endocrine Society, pp. 712-716.		
CM	Haynes et al; <u>"Thyroid and AntiThyroid Drugs"</u> Goodman & Gilman's 7 th Edition, Chapter 60, pp. 1389-1411.		
CN	<u>"Thyroid and AntiThyroid Preparations"</u> Encyclopedia of Chemical Technology, Vol. 23, pp. 1-17.		
CO	Bracco et al, Institute of Physiology, University of Lausanne (D.B., Y.S., E.J.), Lausanne; and the Thyroid Unit, Endocrine Division, University Hospital of Geneva (O.M., H.L., A.G.L.B.), Geneva Switzerland, <u>"Comparison of the Metabolic and Endocrine Effects of 3,5,3'-Triiodothyroacetic Acid and Thyroxine"</u> Journal of Clinical Endocrinology and Metabolism Copyright 1993 by The Endocrine Society, Vol 77, No. 1, pp. 221-228.		
CP	Liang et al; <u>"Organ-Specific Effects of 3,5,3'-Triiodothyroacetic Acid in Rats"</u> Society of the European Journal of Endocrinology, ISSN 0804-4643, pp. 537-544.		
CQ	Safran et al; <u>"Structural Requirements of Iodothyronines for the Rapid Inactivation and Internalization of Type II Iodothyronine 5'-Deiodinase"</u> The Journal of Biological Chemistry 1993, Vol. 265, No. 19, Issue of July 5, pp. 14224-14228, 1993, by the American Society for Biochemistry and Molecular Biology, Inc.		
CR	<u>Sigma-Aldrich Catalogue</u> , Alphabetical List of Compounds – SAF Bulk Chemicals, pp. 971 and pp. 1008		
CS	Everts et al; Department of Internal Medicine, Erasmus University Medical School, Rotterdam, The Netherlands, <u>"Uptake of 3,3' 5,5'-Tetraiodothyroacetic Acid and 3,3',5'-Triiodothyronine in Cultured Rat Anterior Pituitary Cells and Their Effects on Thyrotropin Secretion"</u> . Endocrinology 1995;135(10): pp. 4454-4461.		
CT	Burger et al; <u>"The Effects of Tetraiodothyroacetic and Triiodothyroacetic Acids on Thyroid Function in Euthyroid and Hyperthyroid Subjects"</u> . Acta Endocrinologica 1979; (92)455-467.		
	EXAMINER:		DATE: